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REMARKS

Claims 1, 2, 4-35 and 37-41 are pending in this application, claims 3 and 36 having been canceled without prejudice or disclaimer. Claims 2, 8, 14 and 32 have been withdrawn from consideration.

Claim 31 has been allowed.

Claim 35 is objected to and has been amended to incorporate the subject matter of claims 1, 33 and 34.

Claims 37 and 38 have been amended to correct the claim dependency.

The amendment to claim 1 is made without prejudice or disclaimer. Support for this amendment can be found, for example, in original claim 3 and paragraph [0023] of the specification. See also paragraph [0079] and Figs. 3E and 4E of the specification.

No new matter is added.

Rejection in view of Bates et al. and Sheu et al.

Claims 1, 3-7, 9-13, 15-30, 33 and 34 have been rejected under 35 U.S.C. 103 as being unpatentable over Bates et al. 6,530,951 (Bates) in view of Sheu et al. 5,837,377 (Sheu). Applicant respectfully traverses this rejection and its supporting remarks.

The examiner has relied on the embodiment of Bates illustrated in Figures 8-10D. In this regard, there is disclosed a metal substrate **14** with depressions or wells **28** and **28'**. The wells **28** and **28'** may contain a bioactive material **18**. The bioactive material **18** is separated from the exterior environment by a porous layer **20** through which the bioactive material diffuses and which controls the release of the bioactive material. See, e.g., col. 18, lines 54-55 and Bates Abstract ("[t]he porous layer **20** is comprised of a polymer ... and provides a controlled release of the bioactive material.")

The coating layers disclosed are not polyelectrolytes and there is no criticality to their composition except that layer **20** must be porous and control release of the bioactive agent. In fact the various coating layers may be formed from the same polymer. See, for example, col. 20, lines 42-64.

There is no suggestion in this reference to use the polyelectrolyte layers of the instant claims, much less a multilayer coating region like that currently claimed.

There is no disclosure of ceramic substrates.

Sheu discloses medical articles, including contact lenses, having polyelectrolyte coatings for the purpose of rendering them hydrophilic. The article comprises a "substrate", an "ionic polymer layer" and a "disordered polyelectrolyte coating". The coating must include at least one infiltrating or intermixed polyelectrolyte. See, for example, column 1, line 59, to column 2, line 19. An example of what is meant by infiltrating is given at col. 8, lines 1-8, in which the polymeric layer is a hydrogel polymer or copolymer and the solvent system is chosen to cause the polymeric layer to swell, thereby allowing one or more polyelectrolytes to penetrate or infiltrate the polymeric layer.

The polyelectrolyte coating may contain charge-neutral additives that enhance biocompatibility or that are bioactive, such as heparin. See col. 1, line 66 to col. 2, line 1 and col. 7, lines 47-49. Bates does not, however, teach or suggest that such additives are released from the polyelectrolyte coating, much less that the polyelectrolyte coating is useful to *control* the release of the bioactive agents.

Ceramic substrates are broadly disclosed in Sheu, but there is no disclosure of any type article that could utilize a ceramic substrate.

The Office has urged that it would have been obvious to modify the material property of the polymeric cover of Bates with the polyelectrolyte material of Sheu in order to create a more versatile, biocompatible surface capable of being adsorbed by water.

However, Sheu teaches that these "ionically bonded" coatings are resistant to changes in pH, elevated temperatures, exposure to detergents or organic solvents, mechanical stress, abrasion and repeated ultrasonic washings. See, col. 3, lines 21 *et seq.*

Furthermore, in Bates, a porous polymer layer is used to carefully control the release rate of an underlying bioactive material over both the short term and the long term. See, e.g., col. 7, lines 46-48. In order to permit careful control of the release rate, Bates teaches that the porous polymer layer is deposited *over* the bioactive material, rather than dispersing the bioactive material within or through it. Bates, col. 13, lines 1-6. If the device of Bates were modified in accordance with the teachings of Sheu, however, the addition of an ionic polymeric layer and a disordered polyelectrolyte coating, which structure is noted in Sheu to be very stable, would interfere with that control.

Furthermore, there is nothing in the references themselves to suggest that one of ordinary skill in this art would have been motivated to make the articles of Bates more hydrophilic or to make them using ceramic substrates (see claim 12).

Accordingly, to arrive at the subject matter presently claimed would require, at the very least, undue hindsight of the type proscribed by precedent. See, merely for example, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985). See also MPEP 2142, second paragraph.

Furthermore, neither reference teaches disposing a therapeutic agent within depressions beneath a multilayer coating region, wherein the multilayer coating region extends over the therapeutic-agent-containing surface depressions to provide enclosed cavities which are occupied by the therapeutic agent, as is claimed in claim 1.

Moreover, neither reference teaches a biodisintegrable polyelectrolyte multilayer coating region as claimed in claims 4, 12-17, 20, 30 and 40. Indeed, the disordered polyelectrolyte coating of Sheu is quite stable, resistant even to changes in pH, elevated temperatures, exposure to detergents or organic solvents, mechanical stress, abrasion and repeated ultrasonic washings.

A biodisintegrable polyelectrolyte multilayer coating region as currently claimed is beneficial in that one is eventually left with a bare ceramic or metallic structure sequent. As noted in paragraph [0004], metallic and ceramic structures are robust, resulting in excellent resistance against mechanical damage. Moreover, they are frequently more biologically inert than polymers, and in some cases are bioactive. Furthermore, metallic and ceramic structures can be made porous, thereby enabling them to hold large amounts of drugs.

To summarize, there is no suggestion or reasonable motivation to combine the two reference teachings, and their combination would not result in the here-claimed invention. Thus, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. 103 are respectfully requested.

Allowable Subject matter

Claim 31 has been allowed.

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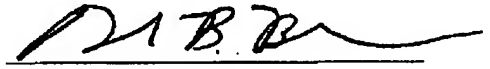
Claim 35 is objected to and has been amended to incorporate the subject matter of claims 1, 33 and 34.

Conclusion

In view of the above, Applicant submits that the pending are in condition for allowance. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

All fees due and owing in respect to this Amendment may be charged to deposit account number 50-1047.

Respectfully submitted,



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